**Exhibit #1**

## 510(K) SUMMARY

JAN 2 5 2013

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: K123008

1. Submitter's Identification:

BIONIME CORPORRATION
NO 694, RENHUA ROAD, DALI DIST., TAICHUNG CITY, TAIWAN 412
Contact Person: Mr. Roy Huang
Phone Number: 886-4-24951268
FAX Number: 886-4-24952568

Date Summary Prepared: September 24, 2012

2. Name of the Device:
Rightest Blood Glucose Monitoring System GM700
GE200 Blood Glucose Monitoring System
Rightest Blood Glucose Monitoring System GM650
GE300 Talking Blood Glucose Monitoring System

3. Common or Usual Name: Glucose test system

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| NBW; System, Test, Blood Glucose, Over-the-Counter | Class II | 21 CFR 862.1345 | Clinical Chemistry 75 |
| LFR; Glucose Dehydrogenase, Glucose | Class II | 21 CFR 862.1345 | Clinical Chemistry 75 |

4. Device Description:

4.1 Our Rightest Blood Glucose Monitoring System GM700 consists of the following devices: Rightest Blood Glucose Meter GM700, Rightest Blood Glucose Test Strip GS700, Rightest Control Solution GC700, lancing device and sterile lancets. The Rightest Blood Glucose Meter GM700, Rightest Blood Glucose Test Strips GS700, and Lancing Device are manufactured by BIONIME Corporation. The Rightest Blood Glucose Meter GM700, when used with the Rightest Blood Glucose Test Strips GS700, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM700 is verified by the Rightest Control Solution GC700.

4.2 Our GE200 Blood Glucose Monitoring System consists of the following devices: GE200 Blood Glucose Meter, GE200 Blood Glucose Test Strip, GE200 Control Solution, lancing device and sterile lancets. The GE200 Blood Glucose Meter, GE200 Blood Glucose Test Strips, and Lancing Device are manufactured by BIONIME Corporation. The GE200 Blood Glucose Meter, when used with the GE200 Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the GE200 Blood Glucose Monitoring System is verified by the GE200 Control Solution.

4.3 Our Rightest Blood Glucose Monitoring System GM650 consists of the following devices: Rightest Blood Glucose Meter GM650, Rightest Blood Glucose Test Strip GS650, Rightest Control Solution GC650, lancing device and sterile lancets. The Rightest Blood Glucose Meter GM650, Rightest Blood Glucose Test Strips GS650, and Lancing Device are manufactured by BIONIME Corporation. The Rightest Blood Glucose Meter GM650, when used with the Rightest Blood Glucose Test Strips GS650, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM650 is verified by the Rightest Control Solution GC650.

4.4 Our GE300 Talking Blood Glucose Monitoring System consists of the following devices: GE300 Talking Blood Glucose Meter, GE300 Talking Blood Glucose Test Strip, GE300 Series Control Solution, lancing device and sterile lancets. The GE300 Talking Blood Glucose Meter, GE300 Talking Blood Glucose Test Strips, and Lancing Device are manufactured by BIONIME Corporation. The GE300 Talking Blood Glucose Meter, when used with the GE300 Talking Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the GE300 Talking Blood Glucose Monitoring System is verified by the GE300 Series Control Solution.

5. Intended Use:

5.1 The Rightest Blood Glucose Monitoring System GM700 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM700 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM700 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM700 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS700 are for use with the Rightest Blood Glucose Meter GM700 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

5.2 The GE200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE200 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE200 Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE200 Blood Glucose Test Strips are for use with the GE200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

5.3 The Rightest Blood Glucose Monitoring System GM650 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM650 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM650 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM650 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS650 are for use with the Rightest Blood Glucose Meter GM650 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

5.4 The GE300 Talking Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE300 Talking Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE300 Talking Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE300 Talking Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE300 Talking Blood Glucose Test Strips are for use with the GE300 Talking Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

6. Predicate Device Information:

The Rightest Blood Glucose Monitoring System GM700 and the GE200 Blood Glucose Monitoring System are substantially equivalent to the brand of Rightest Blood Glucose Monitoring System noted below.

Name: Rightest Blood Glucose Monitoring System GM700
Device Company: Bionime Corporation
510(K) Number: K110737.

The Rightest Blood Glucose Monitoring System GM650 and the GE300 Talking Blood Glucose Monitoring System are substantially equivalent to the brand of Rightest Blood Glucose Monitoring System noted below.

Name: Rightest Blood Glucose Monitoring System GM650
Device Company: Bionime Corporation
510(K) Number: K120423.

7. Comparison to Predicate Devices:

Specification Comparison

| Item | New Device | | Predicate Device |
|---|---|---|---|
| | GE200 | Rightest GM700 | Rightest GM700 (k110737) |
| Similarities | | | |
| Test Time | 5 seconds | | |
| Measuring Range | 20-600 mg/dL | | |

| | | |
|---|---|---|
| Hematocrit Range | 30 - 55% | |
| Operating Relative Humidity Range | 10 ~ 90% | |
| Operating Temperature Range | 43 ~111 °F (6 ~ 44°C ) | |
| Battery Life | About 1000 tests | |
| Monitor | LCD display | |
| Memory Capacity | 1000 blood glucose test results with date and time | |
| Coding | Auto coding | |
| Meter Storage Conditions | 14 ~140 °F (-10 ~ 60°C ) | |
| Test Strip Storage Conditions | 39 ~86 °F (4 ~ 30°C ), < 90% relative humidity | |
| The unit of measurement data | Fix on mg/dL | |
| Sample | Capillary whole blood | |
| Measurement Technology | Dehydrogenase Electrochemical Sensor | |
| Differences | | |
| Minimum Sample Volume | 0.75 microliter | 1.0 microliter |
| Interference | Uric acid ≧ 16 mg/dL<br>Xylose ≧ 10 mg/dL<br>Ascorbic acid ≧ 3 mg/dL<br>Dopamine HCl ≧ 1.25 mg/dL<br>L-Dopa ≧ 2 mg/dL | Uric acid ≧ 10 mg/dL<br>Xylose ≧ 10 mg/dL |
| Strip Reagent | 1.FAD-glucose Dehydrogenase (FAD-GDH) 12.1%<br>2.Potassium ferricyanide 48.5%<br>3.Non-reactive ingredients 39.4% | 1.FAD-glucose Dehydrogenase (FAD-GDH) 9.0%<br>2.Potassium ferricyanide 53.7%<br>3.Non-reactive ingredients 37.3% |
| Power Supply | Two CR2032 batteries | One CR2032 batteries |
| Meter Dimension | 96mm*46mm*17.5mm | 98 mm × 46 mm × 17.5 mm |
| Meter Weight | 65.0 ± 5 g with batteries | 57.0 ± 5 g with batteries |
| LCD display area | 37 mm × 55mm | 32 mm × 52mm |

| | | |
|---|---|---|
| Backlight | Yes | No |
| Control solution | Level 1, 2 and 4 | L1, L2, L3, L4, L5 |

Specification Comparison

| Item | New Device | Predicate Device |
|---|---|---|
| | Rightest GM650 / GE300 Talking | Rightest GM650 (k120423) |
| Similarities | | |
| Minimum Sample Volume | 0.75 microliter | |
| Test Time | 5 seconds | |
| Measuring Range | 20-600 mg/dL | |
| Hematocrit Range | 30 - 55% | |
| Operating Relative Humidity Range | 10 ~ 90% | |
| Operating Temperature Range | 43 ~111 ℉ (6 ~ 44℃ ) | |
| Battery Life | About 1000 tests | |
| Monitor | LCD display | |
| Memory Capacity | 500 blood glucose test results with date and time | |
| Coding | Auto coding | |
| Meter Storage Conditions | 14 ~140 ℉ (-10 ~ 60℃ ) | |
| Test Strip Storage Conditions | 39 ~86 ℉ (4 ~ 30℃ ), < 90% relative humidity | |
| The unit of measurement data | Fix on mg/dL | |
| Sample | Capillary whole blood | |
| Measurement Technology | Dehydrogenase Electrochemical Sensor | |
| Power Supply | Two 1.5V (AAA) batteries | |
| Meter Dimension | 50 mm × 18 mm × 105 mm | |
| Meter Weight | 80.0 ± 5 g with batteries | |
| LCD display area | 48 mm × 34 mm | |

| | | |
|---|---|---|
| Backlight | No | |
| Control solution | Level 1, 2 and 4 | |
| Voice Function | Yes | |
| Data Transmission | Infrared | |
| Stereo jack | Yes | |
| Voice repeat button | Yes | |
| | Differences | |
| Interference | Uric acid ≧ 16 mg/dL<br>Xylose ≧ 10 mg/dL<br>Ascorbic acid ≧ 3 mg/dL<br>Dopamine HCl ≧ 1.25 mg/dL<br>L-Dopa ≧ 2 mg/dL | Uric acid ≧ 10 mg/dL<br>Xylose ≧ 10 mg/dL |
| Strip Reagent | 1.FAD-glucose Dehydrogenase (FAD-GDH) 12.1%<br>2.Potassium ferricyanide 48.5%<br>3.Non-reactive ingredients 39.4% | 1.FAD-glucose Dehydrogenase (FAD-GDH) 9.0%<br>2.Potassium ferricyanide 53.7%<br>3.Non-reactive ingredients 37.3% |

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of the Rightest Blood Glucose Monitoring System GM700, the GE200 Blood Glucose Monitoring System, the Rightest Blood Glucose Monitoring System GM650, and the GE300 Talking Blood Glucose Monitoring System. The evaluation included precision, linearity, interference, sample volume and hematocrit.

9. Conclusions:

Results of performance evaluation of the Rightest Blood Glucose Monitoring System GM700, the GE200 Blood Glucose Monitoring System, the Rightest Blood Glucose Monitoring System GM650, and the GE300 Talking Blood Glucose Monitoring System demonstrate that the devise is substantial equivalence to the predicate

device, Rightest Blood Glucose Monitoring System GM700 and Rightest Blood Glucose Monitoring System GM650.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 25, 2013

Bionime Corporation
c/o MDI Consultant, Inc.
Jigar Shah
55 Northern Blvd, Suite 200
Great Neck, NY 11021

Re: k123008
Trade/Device Name: Rightest Blood Glucose Monitoring System GM700,
GE200 Blood Glucose Monitoring System
Rightest Blood Glucose Monitoring System GM650
GE300 Talking Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: December 27, 2012
Received: December 28, 2012

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

**EXHIBIT B**

## Indications for Use

510(k) Number (if known): k123008

Device Name: **Rightest Blood Glucose Monitoring System GM700**

Indications For Use:

The Rightest Blood Glucose Monitoring System GM700 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM700 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM700 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM700 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS700 are for use with the Rightest Blood Glucose Meter GM700 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Prescription Use _____ AND/OR Over-The-Counter Use ____X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123008

EXHIBIT B

## Indications for Use

510(k) Number (if known): K123008

Device Name: **GE200 Blood Glucose Monitoring System**

Indications For Use:

The GE200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE200 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE200 Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE200 Blood Glucose Test Strips are for use with the GE200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Prescription Use _____ AND/OR Over-The-Counter Use ____X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Office of In Vitro Diagnostics and Radiological Health

510(k) k123008

EXHIBIT B

## Indications for Use

510(k) Number (if known): K123008

Device Name: **Rightest Blood Glucose Monitoring System GM650**

Indications For Use:

The Rightest Blood Glucose Monitoring System GM650 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM650 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM650 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM650 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS650 are for use with the Rightest Blood Glucose Meter GM650 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Prescription Use _____ AND/OR Over-The-Counter Use ____X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) k123008

EXHIBIT B

## Indications for Use

510(k) Number (if known): K123008

Device Name: **GE300 Talking Blood Glucose Monitoring System**

Indications For Use:

The GE300 Talking Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE300 Talking Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE300 Talking Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE300 Talking Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE300 Talking Blood Glucose Test Strips are for use with the GE300 Talking Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Prescription Use _____ AND/OR Over-The-Counter Use ____X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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